Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009

Message Text

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PAGE 01 STATE 178325
ORIGIN HEW-06

INFO OCT-01 EA-09 ISO-00 OES-07 EUR-12 MED-03 ARA-14
NEA-10 /062 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:PFF
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH:RBUHRICH, M.D.
EA/J:HNELSON (INFO)
EUR/NE:JSHUMATE (INFO)
EA/IMS:ADORNHEIM (INFO)
----------011243 300033Z /72
P 291940Z JUL 77
FM SECSTATE WASHDC
TO AMEMBASSY TOKYO PRIORITY
AMCONSUL HONG KONG PRIORITY
AMEMBASSY JAKARTA PRIORITY

UNCLAS STATE 178325

E.O. 11652: N/A

TAGS: TC, OGEN, ETRD, EIND, SWEL, TBIO, XB, XM, GW, SW,

SUBJECT: FDA ADVISORY - HYPOTENSIVE REACTIONS FOLLOW-
ING ADMINISTRATION OF PLASMANATE - RECALL NO. B015-7

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: PLASMANATE, PLASMA PROTEIN FRACTION
(HUMAN) P.P.F.(H) 5 . LIQUID FORM FOR INTRAVASCULAR
ADMINISTRATION. ALL LOTS, EXCLUDING THOSE PREPARED FOR THE
AMERICAN RED CROSS, BETWEEN AND INCLUDING M5089-M6288 AND
ALL LOTS BETWEEN AND INCLUDING NC1076-NC2268. PRODUCT IS
ADMINISTERED INTRAVENOUSLY TO EXPAND BLOOD VOLUME, TREAT
SHOCK, SEVERE BURNS, HYPOPROTEINEMIA, HYPOALBUMINEMIA,
AND CARDIOVASCULAR SURGERY.
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MANUFACTURER/RECALLING FIRM: CUTTER LABORATORIES, 4TH AND
PARKER STREET, BERKELEY, CALIFORNIA, 94710.

2. REASON FOR RECALL: ALL OF THE PRODUCT MANUFACTURED BY
A NEW MODIFIED METHOD (DESIGNED TO REDUCE BRADYKININ LEVEL
OF THE PRODUCT) HAS BEEN IMPLICATED TO HAVE CAUSED AN

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INCREASED NUMBER OF HYPOTENSIVE REACTIONS. THESE REACTIONS HAVE INVOLVED MANY PATIENTS IN A MULTIPLE NUMBER OF HOSPITALS. SUCH ADVERSE REACTIONS PRESENT SERIOUS HEALTH HAZARD TO PATIENT RECEIVING PRODUCT SINCE PATIENT IS ALREADY IN PHYSICAL STATUS WHEREANY ADDITIONAL PROBLEM IS POTENTIALLY LIFE THREATENING.

POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE BEEN NOTIFIED BY CUTTER LABORATORIES OF THE RECALL AND IF THEY HAVE RECEIVED SHIPMENTS OF PLASMANATE FROM LOTS CITED ABOVE. THE FIRM IS RECALLING THE AFFECTED LOTS TO THEIR OVERSEAS (FOREIGN) DISTRIBUTION CENTERS. THE FIRM WILL THEN DETERMINE WHETHER THEY WILL RECONDITION OR DESTROY THE PLASMINATE 5 SEQUESTERED.

FOREIGN CONSIGNEES AS FOLLOWS:
LOTS SHIPPED TO JAPAN - PRODUCT CODE 613-70

M 5304 NC 1096 NC 1135
M 5955 NC 1106 NC 1136
M 5957 NC 1107 NC 1137
M 5959 NC 1111 NC 1138
NC 1076 NC 1112 NC 1145
NC 1078 NC 1114 NC 1148
NC 1079 NC 1115 NC 1149
NC 1080 NC 1117 NC 1151
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NC 1082 NC 1118 NC 1160
NC 1084 NC 1119 NC 1161
NC 1088 NC 1127 NC 1162
NC 1-89 NC 1128 NC 1163
NC 1090 NC 1130 NC 1164
NC 1093 NC 1131 NC 1165
NC 1095 NC 1132 NC 1167
NC 1168

LOTS SHIPPED TO HONG KONG - PRODUCT CODE 613-25

M 5505 M 5857
M 5613 M 5971
M 5713 M 5980
M 5753 M 6019
M 5819 M 6136

LOTS SHIPPED TO TAIWAN

PRODUCT CODE 613-20: M 5692
PRODUCT CODE 613-25: M 5613
M 5857

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M 5863
M 6047
M 6052
M 5716
M 5861 .C ASSIFIED
OTS SHIPPED TO THAILAND

PRODUCT CODE 613-25: M 5861

LOTS SHIPPED TO INDONESIA

PRODUCT CODE 613-25: M 5286

LOTS SHIPPED TO JAMAICA
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PRODUCT CODE 613-25: M 5713
M 5970
M 5993
M 6047
M 6052
M 6089

LOTS SHIPPED TO U.A.E.

PRODUCT CODE 613-25: M 5428

LOTS SHIPPED TO ARMACO

PRODUCT CODE 613-25: M 6136

LOTS SHIPPED TO PHILIPPINES

PRODUCT CODE 613-25: M 5613
M 5863

LOTS SHIPPED TO SINGAPORE

PRODUCT CODE 613-25: M 5984
M 6136

LOTS SHIPPED TO SWEDEN

PRODUCT CODE 613-20: M 5692

PRODUCT CODE 613-25: M 6025 M 6047
M 6052

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PRODUCT CODE 613-27: M 5865 M6I05
M 6151 M 6260

LOTS SHIPPED TO NICARAGUA

PRODUCT COCE 613-20S: M 5692

LOTS SHIPPED TO REPUBLICA DOMINICANA

PRODUCT CODE 613-20S: M 5692
PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO GUATEMALA

PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO BELIZE

PRODUCT CODE 613-25: M 5973

LOTS SHIPPED TO COLOMBIA

PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO VENEZUELA
PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO GERMANY
PRODUCT CODE 6I3-25: M 5365 PRODUCT CODE 613-25G: M 6005
M 6109
M 6147

LOTS SHIPPED TO REPUBLICA DE PANAMA, F. ICAZA & CIA S.A.

PRODUCT CODE 613-25S: M 5739

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LOTS SHIPPED TO ECUADOR

PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO REPUBLICA DE PANAMA, CAJA DE SEGURA
SOCIAL

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PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO EL SALVADOR

PRODUCT CODE 613-20S: M 5692 PRODUCT CODE 613-25S: M 5739

LOTS SHIPPED TO ARGENTINA
PRODUCT CODE 613-27: M5739
LIST OF INTERNATIONAL CONSIGNEES:

DR. MICHAEL UESSON, PRES.
CORTEC AKTIEBOLAG
TORGGATAN 4
(BOX 5077)
20071 MALMO 5
SWEDEN

MINISTRY OF HEALTH
P.O. BOX 233
ABUDHABI, U.A.E.

LUEN CHEONG HONG, LTD.
CALTEX HOUSE, 17TH FLOOR
258 HENNESSY ROAD, WANCHAI
HONG KONG

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UNITED ITALIAN TRADING CORPORATION, LTD.
P.O. BOX 2536
SINGAPORE, 11

PRADJA PHARMACEUTICAL INDUSTRIES
JLN. SEMBOJA 1C
P.O. BOX 2684
JAKARTA, INDONESIA

ABUTA DEVELOPMENT CO., LTD.
5TH FLOOR 63 -- I CHANG AN RD. E. SEC-1
TAIPEI, TAIWAN R.O.C.

TIHUA PHARMACEUTICAL CO., LTD.
24-30 SURIWONGSE RD.
BANGKOK 5, THAILAND

ITAN SHING TRADING COMPANY, LTD.
P.O. BOX 1617
TAIPEI, TAIWAN

BAYER PHARMACEUTICALS, INC.

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COMMERCIAL CENTER
P.O. BOX 854
MAKATI, RIZAL. D-708
PHILIPPINES

COMMERCIAL FARMACEUTICA, S.A.
APARTADO 74
MANAGUA, NICARAGUA

TROPONWERKE
ABT. VERTRIEB CUTTER
BERLINER STRASSE 156
5000 KOLN 80
FEDERAL REPUBLIC OF GERMANY
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VANCE

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Sent Date: 29-Jul-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE178325
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:PFF
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770273-0379
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977073/aaaaaclr.tel
Line Count: 300
Litigation Code IDs:
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Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 08ce5b65-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 6
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 16-Feb-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 1779922
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - HYPOTENSIVE REACTIONS FOLLOW- ING ADMINISTRATION OF PLASMANATE - RECALL NO. B015-7
TAGS: OGEN, ETRD, EIND, SWEL, TBIO, TC, XB, XM, GE, SW
To: TOKYO HONG KONG MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/08ce5b65-c288-dd11-92da-001cc4696bcc
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